



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,190	11/25/2003	Malka Berndt	06530.0317	4220

22852 7590 11/13/2006

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
LLP  
901 NEW YORK AVENUE, NW  
WASHINGTON, DC 20001-4413

EXAMINER

TOY, ALEX B

ART UNIT PAPER NUMBER

3739

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/720,190

**Applicant(s)**

BERNDT, MALKA

**Examiner**

Alex B. Toy

**Art Unit**

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-10, 12-16, 18-24, 26-29, 31-39, 43, 45-53 and 55-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16, 18-23, 35 and 38 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 7, 8, 10, 12-15, 24, 26, 27, 29, 31, 32, 34, 36, 37, 39, 43, 45-50, 52, 53 and 55-59 is/are rejected.
- 7) ☒ Claim(s) 3, 5, 9, 28, 33, 51 and 60 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

This Office Action is in response to applicant's amendment filed on August 31, 2006. The objection to the drawings is withdrawn in view of applicant's submission of new Figure 5. All previous prior art rejections are withdrawn, but new grounds of rejection are made.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24, 26, 27, 29, 31, 32, 36, 52, 53, and 55-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Woloszko (U.S. PGPub 2004/0186469 A1).

Regarding claim 24, Woloszko discloses a method of determining a state of a medical device, the method comprising:

providing a medical device having an indicator printed directly on a portion of the medical device (pg. 11, ¶ 112 and Fig. 9B), the indicator including a chemical capable of undergoing a color change when exposed to a particular environment, and the indicator

is configured to change color after a single exposure to the particular environment (pg. 11-12, ¶ 114, 116); and

viewing the medical device to determine if the indicator has changed color due to exposure to the particular environment (pg. 11-12, ¶ 114, 116 and Fig. 9B).

Regarding claim 26, Woloszko further discloses that viewing the medical device includes determining if there is a symbol on the device (Fig. 9B).

Regarding claim 27, Woloszko further discloses that the particular environment includes a chemical, since the device changes color in response to a rise in tissue temperature.

Regarding claim 29, Woloszko further discloses that the particular environment includes radiation, since heat comprises radiation.

Regarding claim 31, Woloszko further discloses that viewing the medical device includes determining if the indicator is a different color than the portion of the medical device (pg. 12, ¶ 116). Since Woloszko discloses that the indicator may be invisible unless the device is at a specific temperature, Woloszko inherently discloses that viewing the medical device includes determining if the indicator is a different color than the portion of the medical device.

Regarding claim 32, Woloszko further discloses that the medical device includes a plurality of indicators and viewing the medical device includes determining if any one of the plurality of indicators has changed color (pg. 12, ¶ 116).

Regarding claim 36, Woloszko further discloses that the indicator is stationary relative to the device during the color change (Fig. 9B).

Regarding claim 52, see the preceding rejections of claims 24 and 32.

Regarding claim 53, Woloszko further discloses that a first of the plurality of indicators is configured to change color when exposed to a first environment and not change color when exposed to a second environment different from the first environment, and a second of the plurality of indicators is configured to change color when exposed to the second environment and not change color when exposed to the first environment. Woloszko discloses that of a plurality of thermochromic temperature indicator numbers, all numeric values other than that indicative of the actual temperature condition may be invisible (pg. 12, ¶ 116).

Regarding claim 55, see the preceding rejections of claims 31 and 52.

Regarding claim 56, see the preceding rejections of claims 24 and 52.

Regarding claim 57, see the preceding rejection of claim 52 and only the part of the rejection of claim 15 that corresponds to Woloszko.

Regarding claim 58, see the preceding rejections of claims 36 and 52.

Regarding claim 59, see the preceding rejections of claims 24 and 52.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 4, 8, 10, 12, 13, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Truckai (U.S. PGPub 2003/0216732 A1) in view of Truckai (U.S. PGPub 2003/0220637 A1)).

Regarding claim 1, Truckai ('732) discloses a device to perform a medical procedure comprising:

a medical device 580 (Fig. 25); and

an indicator 525 produced directly on the medical device, the indicator including a chemical capable of undergoing a color change when exposed to a particular environment (pg. 13, ¶ 142-143 and Fig. 24),

wherein the indicator is configured to be substantially the same color as a portion of the medical device before being exposed to the particular environment, and the indicator is configured to change color after a single exposure to the particular environment (pg. 13-14, ¶ 144).

Since Truckai ('732) discloses that the thermochromic chemical indicator can change from translucent to red, the indicator effectively has the same color as the medical device before being exposed to the particular environment.

The claim differs from Truckai ('732) in calling for the indicator to be printed on the device. Truckai ('637), however, discloses creating a thermochromic chemical indicator coating analogous to that of Truckai ('732) by printing a thermochromic ink layer 512 (pg. 13-14, ¶ 145 and Fig. 26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have printed the thermochromic indicator on the device of Truckai ('732) in view of the teaching of (Truckai '637) as an obvious way of creating a thermochromic indicator coating that is known in the art.

Regarding claim 2, Truckai ('732) further discloses that the medical device comprises a handle, a distal end effector, and an elongate portion connecting the handle to the distal end effector (Fig. 25).

Regarding claim 4, Truckai ('732) further discloses that the handle comprises a ring portion and an elongate portion (Fig. 25).

Regarding claim 8, Truckai ('732) further discloses that the particular environment includes a chemical, since the device changes color in response to a rise in tissue temperature.

Regarding claim 10, Truckai ('732) further discloses that the particular environment includes radiation, since heat comprises radiation.

Regarding claim 12, Truckai ('732) further discloses that the indicator is configured to be a different color than a portion of the medical device after being exposed to the particular environment (pg. 13-14, ¶ 144).

Regarding claim 13, Truckai ('732) further discloses that the indicator is produced directly on a surface of the medical device (pg. 13, ¶ 142-143 and Fig. 24).

Regarding claim 34, Truckai ('732) further discloses that the indicator is stationary relative to the device during the color change (Fig. 24).

Claims 7, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Truckai ('732) in view of Truckai ('637) and further in view of Woloszko ('469).

Regarding claim 7, the claim differs from Truckai ('732) in view of Truckai ('637) in calling for the indicator to show a symbol when it undergoes the color change. Woloszko, however, teaches using thermochromic indicators that show numeric temperature values when they undergo the color change in order to directly indicate the temperature on the device (pg. 12, ¶ 116 and Fig. 9B). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used thermochromic indicators in the device of Truckai ('732) in view of Truckai ('637) that show a symbol when they undergo the color change further in view of the teaching of Woloszko in order to directly indicate the temperature on the device.

Regarding claim 14, the claim differs from Truckai ('732) in view of Truckai ('637) in calling for the indicator to include a plurality of indicators. Woloszko, however, teaches a plurality of thermochromic indicators in order to indicate multiple temperature thresholds instead of just one (pg. 11-12, ¶ 114, 116 and Figs. 9A-B). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a plurality of thermochromic indicators in the device of Truckai



Art Unit: 3739

('732) in view of Truckai ('637) further in view of the teaching Woloszko in order to indicate multiple temperature thresholds instead of just one.

Regarding claim 15, Woloszko further discloses that each of the plurality of indicators undergoes a color change different from the other of the plurality of indicators (pg. 11-12, ¶ 114).

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Truckai ('732) in view of Truckai ('637) and further in view of le (U.S. PGPub 2003/0036747 A1).

Regarding claim 37, the claim differs from Truckai ('732) in view of Truckai ('637) in calling for the chemical to be configured to change to a first color when exposed to a first environment and change to a second color different from the first color when exposed to a second environment different from the first environment. le, however, teaches using a thermochromic chemical that changes from purple in varying degrees depending upon temperature to bright pink or red (pg. 2, ¶ 30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a thermochromic chemical in the device of Truckai ('732) in view of Truckai ('637) that changes colors as claimed further in view of the teaching of le as an obvious alternate thermochromic chemical for indicating gradations in temperature change that is known in the art.

Claims 39, 43, and 45-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woloszko ('469) in view of le ('747).

Regarding claim 39, the claim differs from Woloszko in calling for the chemical to be configured to change to a first color when exposed to a first environment and change to a second color different from the first color when exposed to a second environment different from the first environment. Ie, however, teaches using a thermochromic chemical that changes from purple in varying degrees depending upon temperature to bright pink or red (pg. 2, ¶ 30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a thermochromic chemical in the device of Woloszko that changes colors as claimed further in view of the teaching of Ie as an obvious alternate thermochromic chemical for indicating gradations in temperature change that is known in the art.

Regarding claim 43, see the preceding rejections of claims 24 and 39.

Regarding claim 45, see the preceding rejections of claims 31 and 43.

Regarding claim 46, see the preceding rejections of claims 24 and 43.

Regarding claim 47, see the preceding rejections of claims 32 and 43.

Regarding claim 48, see the preceding rejections of claims 43 and 47 and only the part of the rejection of claim 15 that corresponds to Woloszko.

Regarding claim 49, see the preceding rejections of claims 36 and 43.

Regarding claim 50, see the preceding rejections of claims 24 and 43.

***Allowable Subject Matter***

Claims 3, 5, 9, 28, 33, 51, and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 16, 18-23, 35, and 38 are allowed.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 4382063 A	USPAT	Romito; Vincent A. et al.
US 5359993 A	USPAT	Slater; Charles R. et al.
US 5384264 A	USPAT	Chen; Ted M. et al.
US 5518927 A	USPAT	Malchesky; Paul S. et al.
US 5602040 A	USPAT	May; Keith et al.
US 5657764 A	USPAT	Coulter; Christopher C. et al.
US 5662712 A	USPAT	Pathak; Chandrashekhar P. et al.
US 5739041 A	USPAT	Nazareth; Albert et al.
US 5786220 A	USPAT	Pronovost; Allan D. et al.
US 5900379 A	USPAT	Noda; Hiroto et al.
US 6140136 A	USPAT	Lee; Jin Po
US 6174309 B1	USPAT	Wrublewski; Thomas A. et al.
US 6218189 B1	USPAT	Antonoplos; Patricia A. et al.
US 20020110931 A1	US-PGPUB	Quattrocchi, Richard A. et al.
US 20030036747 A1	US-PGPUB	le, John M. Mc et al.
US 20030216733 A1	US-PGPUB	McClurken, Michael E. et al.
US 20030216724 A1	US-PGPUB	Jahns, Scott E.
US 20040049172 A1	US-PGPUB	Root, Thomas V. et al.
US 20040253142 A1	US-PGPUB	Brewster, Barry Sinclair et al.
US 20040265778 A1	US-PGPUB	Kliff, Howard et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT *AT*  
11/9/06

*Michael Peffley*  
MICHAEL PEFFLEY  
PRIMARY EXAMINER